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Clinical characteristics and 30-day outcomes in patients with acute decompensated heart failure: Results from Indian College of Cardiology National Heart Failure Registry (ICCNHFR)

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ABSTRACT

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[1] The authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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Background: Acute decompensated heart failure (ADHF) is a challenging medical emergency with high mortality and its prevalence is increasing in India. There is paucity of data on ADHF in the country.
Methods: Indian College of Cardiology National Heart Failure Registry (ICCNHFR) is an on-going observational registry on ADHF contributed by 22 hospitals across India; and we present the in-hospital and 30-day outcomes of ADHF patients enrolled from August 2018 to July 2019. Major objective included capturing demographics, comorbid conditions, aetiology, prescription patterns and assessing clinical outcomes.
Results: Of 5269 patients (mean age: 61.90 ± 13.85 years) enrolled in this study, males were predominant (67.09%). Mean duration of hospitalization was 5.74 ± 4.74 days. Ischemic heart disease was the most common (75.44%) aetiology. Abnormal electrocardiogram readings were found in most patients (89.86%). LVEF of <40% was found in 68.29% of patients. In-hospital mortality rates were 6.98%. The 30-day cumulative mortality was 12.35% and 30-day rehospitalization rate was 7.98%. At discharge, all guideline-based medical therapy (GDMT) were prescribed only to 24.99% of patients and 23.72% adhered to the prescription until 30 days. Older age, high serum creatinine levels and poor LVEF contributed to high mortality and rehospitalization.
Conclusion: Patients with ADHF were younger and predominantly males. Usage of GDMT in ADHF patients was low (24.99%) and the in-hospital mortality was high. Older age, high serum creatinine levels, poor LVEF contributed for 30-day mortality and rehospitalization. This data on ADHF, could help in developing strategies to improve outcomes for HF patients in India.

1. Introduction

Acute decompensated heart failure (ADHF) is a life-threatening condition with high mortality and morbidity [1,2]. Despite progress in the overall healthcare system, prevalence of heart failure (HF) continues to rise in India due to increasing cardiovascular (CV) risk factors, better survival rates in coronary syndromes, aging population and increasing prevalence of chronic kidney disease (CKD). According to a South India based study, average total hospitalization expenditure per person on HF was INR 133,663 [3]. High mortality rates and rehospitalization carries an estimated expenditure of $1186 million in India, which is a huge economic burden [3,4]. Hence, there is a need to introduce effective management tools immediately following discharge and during the short-term follow-up [5–8].

Reliable evidence regarding aetiology, management practices and associated outcomes in ADHF admissions in India are lacking [9]. However, a few data on HF are available either from hospital-based studies or from local HF registries [10–13]. As, most of these observations were derived from small cohorts of hospital-based HF registries, they do not reflect the real picture of HF prevalence and its clinical outcomes across India. Moreover, based on disease-specific estimates, an overall prevalence of HF is 1% (8–10 million) and the estimated mortality rate is about 0.1–0.16 million individuals per year in India. However, this could be lower than real-world incidences [14]. Therefore, there is a need to understand patient characteristics, aetiology and clinical outcomes with HF in India to help us better address the gaps in HF care.

With this background, the Indian College of Cardiology National Heart Failure Registry (ICCNHFR) designed a national-level prospective observational registry to assess the data on prevalence, clinical patterns, aetiology, comorbid conditions, in-hospital mortality, re-hospitalization rates, 30-day mortality and prescription patterns in Indian patients with ADHF [15]. The idea in conducting this study is to understand the real-world scenario of ADHF in India. Equipped with such data it would be possible to address these gaps in care which has not been done effectively before.

2. Methods

2.1. Study settings

All major centers in the country with facilities to treat ADHF under the supervision of a cardiologist were invited to join the registry and only those centers which gave a valid consent and cleared by their institutional ethics committee participated. This prospective study was conceived and planned by the ICC; and the design, rationale, inclusion and exclusion criteria have been published [15]. The methodology flow chart is in supplementary material (S1). This prospective observational study enrolled 22 hospitals (private and government, teaching and non-teaching). The list of hospitals and principal investigators (PI) are in the supplementary material (S2). These centers were located in cities and towns catering to a large geographical area and having a sizeable referral from rural areas. This on-going registry is registered under the Clinical Trial Registry of India (Registration No: CTRI/2019/08/020972).

2.2. Study group

The data of consecutive patients admitted with ADHF between 1 August 2018 to 31 July 2019 with class III and IV symptoms in the CCU were analysed. The diagnosis criteria of ADHF were based on ESC guidelines 2012 [16,17] - clinical signs and symptoms of acute HF, supported by echocardiographic evidence in all and/or elevated Brain Natriuretic Peptide (BNP) and N-terminal pro b-type natriuretic peptide (NT-proBNP) in some. Depending on the ejection fraction they were classified into HFrEF (EF <40%) and HFpEF (EF ≥ 40%).

The group were also categorized as

1. De novo HF-New onset or first occurrence of HF
2. Acute on chronic HF-worsening symptoms on previously diagnosed HF

2.3. Data collection

The data was collected using an *E*-CRF that was made accessible through a dedicated software which was password protected, developed by M/S Netbios, on the PHP platform. Before data collection, the software was validated through a pilot study. The study questionnaire is provided in supplementary material (S3).

All participating centers had a Co-investigator (CI), a site coordinator and a nurse / physician in charge to ensure smooth enrollment and for accurate data entry. Every site had training from a central nodal site at Lakshmi Hospital, Palakkad, Kerala in data collection and entry. The CI and site coordinator verified the data. Daily checking of the data and reminders to the investigator by telephone calls and mails for missing data was done. Further clarifications and completion of the data were taken up with the site coordinator periodically. An update on the patient enrollment numbers and status of complete and incomplete data were sent by E-mail every week with a color coding for easy rectification. This database was locked after a prespecified time and no editing of data beyond that period was permitted.

2.4. Study variables

The eCRF captured data on the demographics, comorbid condition, aetiology, laboratory investigation performed, ECG, left ventricular function by echo, inhospital and 30 day outcomes. The basic biochemical tests including serum creatinine was captured at the time of admission. The biomarkers like BNP/NTpro-BNP was not a mandatory column in view of the cost constraints, as many enrollments occurred in the government institution. This was captured in centres wherever it was available.2D echocardiogram was done during admission to capture the left ventricular systolic function (EF) and to identify underlying aetiology. The in-hospital outcome, prescription patterns, usage of guideline-directed medical therapy (GDMT), interventions were also documented. Out of 5279 patients enrolled, 10 were excluded and a total of 5269 were eligible for analysis.

2.5. Study follow-up

The 30th day follow up was documented and follow up continued for a year. The follow up data included adherence to GDMT, rehospitalization and mortality. This data was captured by telephonic contact where the patient did not visit the hospital.

2.6. Ethical clearance

All participating centres had an institutional EC clearance. This study was conducted by adhering to the ethics principles of the Declaration of Helsinki, International Council for Harmonization-Good Clinical Practices (ICH-GCP) guidelines, Indian Council of Medical Research (ICMR) and the Indian Good Clinical Practice (GCP) guidelines.

2.7. Statistical analysis

Continuous variables are described as mean (standard deviation, SD) or as median (interquartile range). Categorical variables are reported as frequency with their percentages. Predictors of clinical events were identified using multivariate regression analysis by considering baseline clinical characteristics as independent variables.

3. Results

3.1. Demographic and clinical characteristics

Of 5269 patients with ADHF admitted to the hospital during the study, 3535 (67.09%) were males and 1734 (32.91%) were females. The mean age of patients was 61.90 ± 13.85 years and the mean duration of hospital stay was 5.74 ± 4.74 days (Table 1).

De novo HF and acute on chronic HF were observed in 1770 (33.59%) and 3499 (66.41%) of patients, respectively. Ischemic heart disease (IHD) was the most common (75.44%) aetiology. Dilated cardiomyopathy (DCM) and rheumatic heart disease (RHD) were present in 12.83% & 4.88% of patients, respectively. Predominant CV risk factors observed included diabetes (51.53%), hypertension (52.27%) and CKD (14.81%). The various comorbidities and aetiology are outlined in (Table 1).

ECG was abnormal in 4722 patients (89.86%) and was predominantly ischemic ST changes. Chamber hypertrophy, bundle branch block and intraventricular conduction defects contributed to 14.11%, 9.33% and 3.96% respectively. Atrial fibrillation (AF) was seen in 8.78% of patients studied (supplementary material - S4). 2D echocardiogram left ventricular ejection fraction (LVEF) of >40% and <40% was seen in 31.71% and 68.29% of patients, respectively (Table 1). The biomarker data was available only in 1503 patients of the total group.

Table 1
Demographics, comorbidities and aetiology.

Variables	Total ($N = 5269$)
Age in years, mean (SD)	61.90 (13.85)
Male, n (%)	3535 (67.09)
Female, n (%)	1734 (32.91)
Urban, n (%)	2446 (46.42)
Rural, n (%)	2823 (53.58)
Type of HF, n (%)	
Abnormal ECG, n (%)	4722 (89.86)
ST changes, n (%)	2580 (48.97)
LVEF, n (%)	
<40%	3545 (68.29)
>40%	1646 (31.71)
De novo HF	1770 (33.59)
Acute on chronic HF	3499 (66.41)
Comorbidities	
Diabetes, n (%)	2706 (51.53)
Hypertension, n (%)	2746 (52.27)
CKD, n (%)	773 (14.81)
COPD, n (%)	495 (9.39)
CVA, n (%)	262 (4.97)
PVD, n (%)	134 (2.54)
CLD, n (%)	38 (0.72)
Cancer (Chemotherapy), n (%)	35 (0.66)
Aetiology of HF, n (%)	
RHD	257 (4.88)
RCM	11 (0.21)
IHD	3975 (75.44)
HTHD	60 (1.14)
DCM	676 (12.83)
CHD	22 (0.42)
Unknown	268 (5.09)

HF: heart failure; ECG: electrocardiogram; CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease: CVA: cerebrovascular accident; PVD: peripheral vascular disease; CLD: chronic liver disease; RHD: rheumatic heart disease; RCM: restrictive cardiomyopathy; IHD: ischemic heart disease; HTHD: hypertensive heart disease; DCM: dilated cardiomyopathy; CHD: congenital heart disease;

3.2. Re-hospitalization and in-hospital and 30-day mortality outcomes

In-hospital mortality was 6.98% ($n = 367$) and the cumulative 30-day mortality rate was 12.02% ($n = 628$) with 7.98% ($n = 380$) rehospitalization rate observed during the 30-day follow-up (Table 2). These patients were followed up for a year. 408 patients (8.33%) were lost for follow up. 463 patients died during the 1 year follow up and the one-year mortality was 20.82%.

3.3. Treatment patterns

The GDMT prescribed at discharge for patients with HFrEF included angiotensin-converting enzyme inhibitor (ACEI)/angiotensin receptor blocker (ARB) (41.18%), beta-blockers (67.18%) and mineralocorticoid receptor antagonists (MRAs) (49.08%). Use of diuretics (87.97%), angiotensin receptor neprilysin inhibitor (ARNI) (2.67%) and ivabradine (13.8%) was also documented. At 30-day follow-up, similar

Table 2
In-hospital and 30-day mortality outcomes and re-hospitalization rates of patients with HF.

Outcome	n (%)
In-hospital mortality, n (%)	367 (6.98)
Mortality at one-month, n (%)	261 (5.37)
Mortality at one-month from baseline, n (%)	628 (12.02)
Rehospitalization within one-month, n (%)	380 (7.98)

HF: heart failure. Of 5260 patients, data of 5224 patients are available at 1-month follow-up i.e. 1-month data not available for 36 patients who were alive at discharge.

percentages of patients received GDMT: ACEI/ARB (42.67%); beta-blockers (68.16%); MRA (Aldactone; 45.97%). Use of diuretics (88.1%), ARNI (2.68%) and Ivabradine (12.95%) remained the same at 30 days. Use of vasodilators like nitrates constituted 26.38% of the entire study group (Fig. 1). At discharge, all GDMT were prescribed only to 24.99% of patients with ADHF and 23.72% patients adhered to the prescription until 30 days.

The data showed device therapy usage in few patients. (ICD, CRT—P, CRT-D and pacemakers in (0.98%, 0.26%, 0.28%, 1.34% respectively). Revascularization like percutaneous coronary intervention (PCI) and coronary artery bypass surgery (CABG) was documented in 8.97%, and 2.35% respectively (supplementary material - S5).

3.4. Predictors of 30-day mortality and 30-day re-hospitalization

Based on our study analysis, older age (65.47; $p \leq 0.0001$), high serum creatinine levels (1.67 mg/dL; $p \leq 0.0001$) and LVEF <40% ($p \leq 0.0001$) were significant predictors of 30-day mortality in patients with HF. Longer durations of admission (6.43 days vs. 5.72 days in non-hospitalized patients, $p = 0.023$) and higher creatinine levels (1.45 mg/dL vs. 1.35 mg/dL in non-hospitalized, $p = 0.044$) were found to be predictors of rehospitalization in patients with HF (Table 3).

Table 3
Predictors of 30-day mortality and 30-day rehospitalization in patients with HF.

Predictors for 30-day mortality in patients with HF			
Characteristics	Deaths ($n = 569$*)	Survival ($n = 4423$*)	*P* value
Age in years, mean (SD)	65.47 (14.31)	61.42 (13.72)	<0.0001
Creatinine value, mean (SD)	1.67 (1.08)	1.35 (0.83)	<0.0001
LVEF, n (%)			
≥40%	127 (8.0)	1468 (92.0)	<0.0001
<40%	442 (13.0)	2955 (87.0)	
Predictors for 30-day rehospitalization mortality in patients with HF			
Characteristics	Rehospitalization ($n = 348$#)	No rehospitalization ($n = 4264$#)	P value
Days admitted, mean (SD)	6.43 (5.73)	5.72 (4.32)	0.023
Creatinine value, mean (SD)	1.45 (0.86)	1.35 (0.85)	0.044

HF: heart failure; LVEF: left ventricular ejection fraction£.

* We have selected patients with data available on most major variables of interest for ease of comparison. However, for some variables, the 'n' is smaller than maximum.

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4. Discussion

Epidemiological transition is increasing the burden of HF in low- and middle-income countries like India [9,18–21]. The Indian College of Cardiology National Heart Failure Registry (ICCNHFR) is a first-of-its-kind study to estimate prevalence, aetiology and treatment patterns of HF across India. Our study demonstrated that Indian patients with HF are younger (predominantly males) unlike patients from other international registries who were 7–10 years older than Indian patients [22,23]. The Indian regional registries such as the Trivandrum Heart Failure Registry (THFR) [10], Kerala acute coronary syndrome (ACS Registry) [24] and treatment and outcomes of acute coronary syndromes in India (CREATE Registry) [25] enrolled younger patients. The sex ratio was unequal amongst patients from the ICCNHFR study, males were predominant (67.09%). In the organized program to initiate lifesaving treatment in hospitalized patients with heart failure (OPTIMIZE-HF) trial [26], acute decompensated heart failure national registry (ADHERE) [23], family-led rehabilitation after stroke in India- acute decompensated heart failure syndromes (ATTEND) [27] registry and in the European Society of Cardiology heart failure (ESC-HF) [28] studies, the proportion of male patients were 48%, 48.4%, 58% and 62.6%, respectively.

In-hospital mortality (6.98%) rates were relatively higher in patients from the ICCNHFR study compared to patients in the western country registries such as ADHERE (4.5%), OPTIMIZE-HF (3.8%) and ESC-HF (4.9%) [23,26,28]. Data from the THFR study showed higher in-hospital mortality rate (8.5%) and 90-day all-cause mortality rate of 2.43 deaths per 1000 person- per year [10].

IHD was observed as the main aetiology of HF in the ICCNHFR (75.44%) study. However, in the ADHERE (coronary artery diseases, 57.5%; AF, 30.9%; chronic obstructive pulmonary disease, 31.4%) and the ESC-HF registries (IHD, 53.8%; AF, 44%; chronic obstructive pulmonary disease, 20%), patients with IHD were less [23,27,28]. In this ADHF study, HFrEF-LVEF <40% (68.29%) was predominantly observed, whereas LVEF <40% was comparatively less in patients from the ADHERE (51.3%), OPTIMIZE-HF (48.6%) and ATTEND (57%) registries

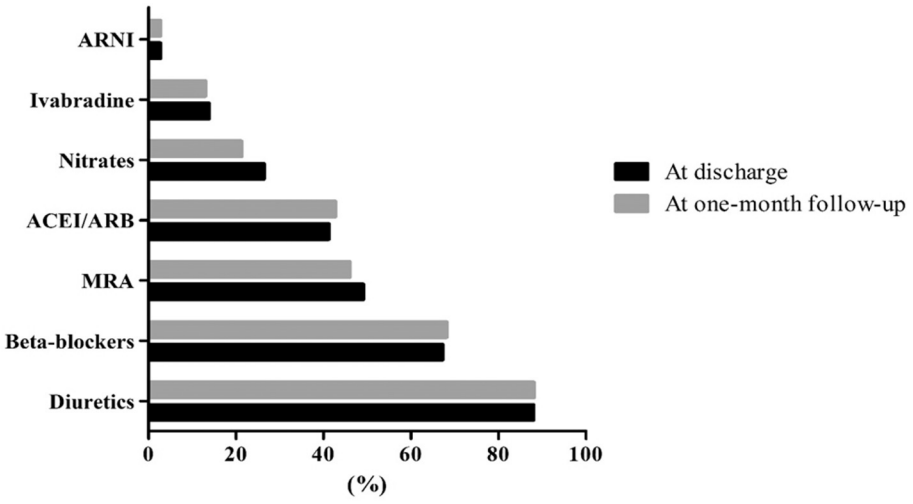

Fig. 1. Prescribed rates of major oral medications in patients with HF at discharge and at 1-month follow-up.
ACEI: angiotensin converting enzyme inhibitor; ARB: angiotensin receptor blocker; ARNI: angiotensin receptor neprilysin inhibitor; MRA: mineralocorticoid receptor antagonists; HF: heart failure.

[23,26,29]. De novo HF cases were relatively higher in our study cohort (33.59%) compared to ADHERE (24%) [23], OPTIMIZE-HF (13%) [26] and the Euro Heart failure survey II (EHFS-II) registries (37%) [30]. Duration of hospital stay was more in patients from the ICCNHFR study (5.74 days) compared to patients in the ATTEND registry (4.3 days). Sicker patients, low LVEF and the presence of comorbidities might be the possible reason for longer hospital stay in our study cohort.

The quality of care in patients with ADHF is poor in low- and middle-income countries compared to high-income countries [31,32]. Because of the poor socio-economic situation, biomarker assessment in all was not feasible. GDMT was proven effective and improved clinical outcomes, reduced in-hospital stay and long-term mortality rates in previous studies including the Asian sudden cardiac death in heart failure (ASIAN-HF) study [23,33]. In our study, the in-hospital mortality rate was 6.98% and the 30-day cumulative mortality rate was 12.37%. Sicker patients with hypotension had higher mortality.

There is scarce data concerning the prescription patterns of GDMT and its associated clinical outcomes in patients with HF in India except for the data available from a few regional HF registries. In the Medanta registry, GDMT with a beta-blocker was prescribed to 81.8% patients despite which the 1-year mortality rate was 17.6% [34]. The THFR study data indicated suboptimal GDMT (only 25% of patients received GDMT at discharge). This was associated with increased likelihood of rehospitalization of patients with HF [35]. However, compared to western country registries, rate of GDMT at discharge was far below in this study (ACEI/ARB, 41.18%; beta-blockers, 67.18%; MRAs, 49.08%). In the ESC-HF registry study [28], AECI/ARB (77%), beta-blockers (77%), MRAs (53.9) and diuretics (83.9%) were prescribed at discharge whereas in ADHERE [23] study, patients with left-ventricular systolic dysfunction were prescribed ACEI/ARB (83.1%), beta-blockers (80.1%) and diuretics (87.2%) at discharge. All GDMT prescriptions were 24.99% at discharge and 23.72% at 30-day follow-up which is comparatively less compared to that reported in western statistics.

Poor prescription rates of GDMT in this study is because of many reasons. Physician inertia and concern of adverse effect in a given patient are major factors. Many patients have bronchospasm and hence the reluctance to use beta blockers in them. For the same reason ivabradine use is more in this cohort. CKD is high and again the usage of ACE(i)/ARB and MRA is less as the worry of worsening renal function is understandable. ARNI use is low because of the high cost. Most of the hospitals have a huge patient turnover and the lack of use of a checklist at discharge is a major factor for poor GDMT prescription. Poor adherence to GDMT and lack of up-titration of therapy is worrisome. A low percentage of insurance coverage, poor financial situation, lack of education and a lack of proper follow up are the main reasons. Multiple drugs prescribed definitely reduces compliance. Our group has shown how a HF specific quality improvement toolkit like simple checklist at discharge and follow up by a nurse could improve the prescription patterns and adherence to GDMT [32].

Moreover, risk factors such as old age, high serum creatinine levels and reduced LVEF were identified as predictors for 30-day mortality in this study. Older age, higher serum creatinine levels, New York Heart Association functional class IV symptoms and suboptimal treatments were associated with higher risk for 90-day all-cause mortality in THFR study [10]. AHEAD (A: atrial fibrillation; H: hemoglobin; E: elderly; A: abnormal renal parameters; D: diabetes mellitus) scoring for HFrEF and heart failure preserved ejection fraction (HFpEF) have been validated in Asians [36]. AF, older age and elevated renal parameters were found to be associated with higher mortality at 30 days. Diabetes and hypertension did not lead to a difference in 30-day mortality ($p = 0.833$ & $p = 0.399$, respectively). Patients who were sicker, having a longer hospital stay and having CKD required rehospitalisation. Few patients did undergo device implantations for heart failure and revasularization procedures. However, their impact on prognosis could be evident only on long term follow up.

4.1. Study limitations

Despite the fact that the data came from several states in India using electronic format, a major study limitation was the fewer number of hospitals involved. Hence, the data reported here might not be a true reflection of the actual ADHF scenario in the entire country. In addition, data was recorded from the cardiac intensive care unit only. As ADHF is a heterogeneous condition, patients with multiple comorbidities could also have presented to different medical departments during the study period. Thus, there could be a presentation bias. Cardiac biomarkers were not captured in every patient and analysed because of financial constraints. The echocardiogram basically looked into the left ventricular systolic function only and a detailed analysis was not available for an in-depth analysis. All these are methodological limitations. The renal parameters and biochemical tests were done during admission. A follow up data on these parameters would have been useful. The dose of GDMT was not available. As such, registry data are prone to bias. Nevertheless, this study is an attempt to understand the demographics, outcome and therapy patterns on ADHF in India.

5. Conclusion

In conclusion, ICCHFR study has shown that hospitalized patients with ADHF were younger and were predominantly men with longer duration of hospital stay and higher in-hospital mortality rate compared to studies from previous international registries. IHD was the most common aetiology. GDMT at discharge was substantially low. Older age, high serum creatinine levels and poor LVEF were predictors of 30-day mortality and rehospitalization in these patients. This data would possibly help in improving HF care.

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Declaration of Competing Interest

The authors report no relationships that could be construed as a conflict of interest.

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Appendix A. Supplementary data

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